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14. ABSTRACT Scientific investigations, product development, and response to threats of endemic diseases and emerging pathogens are undertaken to reduce the risk of infection and lessen the impact of natural occurring or man-made pathogens to humankind. If, however, proper precautions are not taken and safe practices are not utilized there is a risk that these interventions could contribute to increase the potential exposure of individual scientists and technical staff, as well as surrounding communities, to dangerous infectious diseases. The threat is perhaps greatest within the international laboratory community where these dangerous pathogens are routinely manipulated and investigated. This award supports critical training and hands-on experience to predominantly international scientists working with especially dangerous pathogens that require special biocontainment facilities for their safe and secure handling.					
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INTRODUCTION

At the time this report is being written, concerns over laboratory safety at the growing number of biocontainment laboratories in the U.S. and around the world are being proclaimed by elected officials, regulatory agencies, and high profile media. Investigations and hearings are being held to discuss laboratory mistakes, the potential for dangerous exposures, and concerns over transfers of biological agents between laboratories.

At the same time, the need for infectious disease research in high containment laboratories is greater than ever before as scientists push to understand the pathology and develop diagnostics, vaccines and therapeutics for deadly diseases like Ebola. Human mobility means that epidemics that occur in other parts of the world can quickly become problems elsewhere. Ensuring adequate training for the scientists who work in laboratories where dangerous pathogens are studied is the goal of the National Biocontainment Training Center.



Through the aims identified in this project, the NBTC shares the expertise gained through operation of the Galveston National Laboratory (GNL) with others involved in laboratory research. Training the scientists who work in the GNL, and more than five years of operation, have provided unique and valuable expertise that is taught through formal, customized didactic and hands-on training with laboratory personnel, scientists and operations personnel from across the U.S. and around the world.

This annual report describes the training that has been provided between 15 July of 2014 and July 30 of 2015. Training supported by this program since January 2015 has included both domestic and international training, picking up where the companion award (W81XWH-09-2-0053), which expired at the end of 2014, left off. The work described herein supports a coordinated effort to provide critical hands-on training and mentored experience to both national and international scientists who work with dangerous pathogens in biocontainment facilities.

10. Comments on administrative and logistical matters.

Staffing report:

The National Biocontainment Training Center at UTMB benefits from an experienced team of Environmental Health and Safety Professionals, scientists, engineers and technicians to provide unique biosafety training to students, faculty and other professionals who work in biocontainment laboratories. Trainers deliver customized one-on-one training after providing individualized assessments of each student. Currently there are 16 individuals who have received all or part of their salaries from this grant and who participate in the biosafety training for domestic and international scientists and personnel. They include:

James W. Le Duc is the principal investigator for the training center and is responsible for oversight of all program initiatives, institutional collaborations, fiscal management and project reporting.

Dennis Bente provides mentored training to international scientists, including Dr. Han Xia, who are working within the biocontainment laboratories as part of collaborative projects and fellowships. His work focuses on arboviruses, the unique insectaries at the GNL, and filoviruses such as Crimean-Congo Hemorrhagic Fever.

Sophie Brocard provides didactic and mock-laboratory training and is a principal trainer involved in international training in support of the NBTC and other collaborative efforts.

Christopher Gibbs assists in the training of operations personnel, including engineers from domestic and international facilities who benefit from hands-on experience ensuring the safe use, maintenance, and certification of biological safety cabinets.

Miguel Grimaldo assists biocontainment facilities around the world with operational expertise and represents the GNL on the Operations Committee of NIAID's National and Regional Biocontainment Laboratory Network. He is a regular lecturer on the topic of biocontainment engineering and operations.

Jason Hardcastle provides training for the BSL2 Training Course, PAPR Training Course, and the Class III BSC Training Course. He also assists with the ABSL2 Training Course, BSL3 Training Course, and ABSL3 Training Courses.

Vickie Jones is responsible for providing biological and chemical safety training to individuals from academia and industry, including site-specific training.

Tom Ksiazek has more than 30 years of experience in biocontainment research and is one of the world's foremost experts on filoviruses. He is the Director of Biocontainment for the GNL and provides mentored training to all BSL4 trainees.

Sheri Leavitt provides ABSL training to graduate students, faculty and staff who will work in the ABSL laboratories. She is involved in training of new Animal Resource Center staff as well as visiting scientists from around the world.

Mary Milazzo has 18 years of experience in biocontainment research and is the Assistant Director for the GNL's BSL4 laboratory. She supports all aspects of high containment training, from SOP development to *in vivo* and *in vitro* training of scientists and other support staff.

Je T'aime Newton provides facility training for the BSL-4 laboratory and Emerging Infectious Disease(EID) training for Healthcare.

Belinda Rivera is the *in-vivo* training consultant providing oversight and training for ABSL2, ABSL3, ABSL4, and NHP courses for both US and international trainees. As needed, she assists with BSL2 and BSL3 *in-vitro* training courses. She is frequently a presenter at ABSA and AALS meetings.

Nate Schueller provides training for the BSL2 Training Course, ABSL2 Training Course, and the ABSL3 Training Course.

Sharon Walters handles scheduling and administrative duties for all training that is provided through the NBTC.

Han Xia is a post-doctoral fellow from China who is in training with Dr. Dennis Bente under NBTC Aim 3.

Dee Zimmerman monitors developments in biosafety and training and ensures that all training courses include the most up to date biosafety protocols and procedures.

11. Use additional page(s), as necessary, to describe scientific progress for the quarter in terms of the tasks or objectives listed in the statement of work for this assistance agreement.

Background

UTMB's National Biocontainment Training Center offers a portfolio of courses and individualized mentorship training experiences that evolve based on expanding information, the needs of the students, and as new equipment, procedures and regulations are put into place. All students are assessed for existing knowledge and skill prior to the beginning of their training. With this assessment, each student can be trained based on his or her individual needs. This report highlights the training that has been provided to both national and international students throughout this year, including representatives from within the NBL-RBL Network, UTMB students, and representatives from other biocontainment laboratories and regulatory organizations.

The progress detailed here is part of a continuous training process that provides unique training for scientists and laboratory personnel. The overall goal of the NBTC is to enhance global biosecurity and biosafety by ensuring that those who work with dangerous pathogens are well-educated and prepared to work safely in biocontainment facilities.



Initial training of students occurs in the specially designed mock training lab at the National Biocontainment Training Center at the University of Texas Medical Branch in Galveston. Mentored training may be done at UTMB or at a student's home institution.

Aim 1. To provide standards-based biological containment laboratory safety knowledge to international partners.

Ongoing collaborations with institutions around the world are common occurrences for the trainers at the National Biocontainment Training Center at the University of Texas Medical Branch. Training is focused on providing support to personnel who work in facilities that are involved in the study of infectious diseases and research. The unique nature of the NBTC attracts scientists, engineers, and laboratory personnel from institutions and organizations worldwide. In addition to international students, through this Aim, trainers from the NBTC are also working with partner institutions in the United States. Progress on this Aim is reported below:

Center for Technological Development in Health, Brazil -- Engineering Director Miguel Grimaldo and his team continue to communicate and consult with the team of engineers and scientists who are responsible for the BSL3 laboratories that are being designed, constructed, and validated at the Center for Technological Development in Health (CTDS) at Fiocruz, Brazil. Individuals from Brazil completed a week-long training program in Galveston in July 2014, and ongoing consultations to assist with their efforts have continued on a regular basis. This organization is working on translational projects that bring scientific research together with manufacturing and production partners. Ongoing consultations have focused on efforts to install and validate specialized equipment, develop protocols and SOPs for safe laboratory and facility operation, and to expand operational knowledge among the team of technical and engineering personnel at the Center.

Victorian Infectious Disease Reference Laboratory, Melbourne, Australia – Two staff members from the Victorian Infectious Diseases Reference Laboratory (a division of the Doherty Institute at the University of Melbourne), attended training at the National Biocontainment Training Center in Galveston in preparation for working in BSL4 laboratories at the facility. This laboratory provides services to the Department of Health Victoria, Victorian hospitals and clinics, the Commonwealth Department of Health, and the World Health Organization. Additional training on-site in Melbourne, specific to the Personal Protective Equipment and laboratory set-up, is scheduled to take place prior to the opening and commissioning of the new BSL-4 laboratories there.

One Health Summer School – Sokoine University, Morogoro, Tanzania -- Dr. Anne-Sophie Brocard was invited to participate in the Southern African Centre for Infectious Disease Surveillance (SACIDS) 3rd One Health Summer School week in August 2014, focusing on biosafety for high containment laboratory personnel. The course took place at the Sokoine University in Morogoro, Tanzania and involved 25 students representing ten African countries. Those countries included the Democratic Republic of Congo, Kenya, Tanzania, Ethiopia, Uganda, Malawi, South Africa, Zambia, Mozambique, and Mali. Instructors assisting Dr. Brocard with the training came from the United Kingdom, South Africa and Tanzania. This opportunity to train those who will train others provided significant leverage in biosafety training that should have a huge impact on laboratories throughout Africa as those who participated go back to their facilities and train others.

BELOW: Dr. Anne-Sophie Brocard, Director of the National Biocontainment Training Center, is seated front left with representatives of the faculty and the students who were trained at the 3rd SACIDS One Health Summer School on Biosafety in Morogoro, Tanzania August 25th – 30th, 2014.

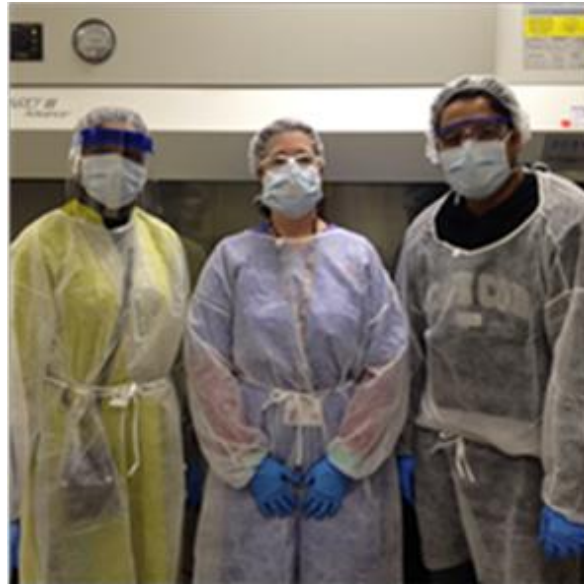


American Biological Safety Association (ABSA) Biosafety Conference – Trainers from the NBTC taught courses at the annual Biosafety Conference, sponsored by ABSA in October 2014. The event was held in San Diego, California, and consisted of three days of education and several pre-conference seminars. High containment and select agent issues were the subject of the international session, which was held on October 5, 2014. In addition, three sessions were led by NBTC personnel: Dr. Anne-Sophie Brocard on “Advanced Risk Assessment,” Ms. Belinda Rivera on “Advanced Principles and Practices of Working in an ABSL3 Laboratory,” and Mr. Miguel Grimaldo on “Lessons Learned in the Operation of BSL3/BSL4 Laboratory Facilities.” Information provided in these sessions assists both domestic and international high containment laboratory personnel in advancing their education. The contents of the sessions also become ABSA resources for sharing with individuals both in the U.S. and abroad.



International Trainees from Pakistan – The NBTC welcomed two students from Aga Khan University who traveled to Galveston in January 2015 to receive nearly three weeks of personalized training at UTMB's National Biocontainment Training Center. The students – a senior technologist and an assistant laboratory manager -- participated in BSL2 and BSL3 training (both theory classes and hands-on training in the mock laboratory), as well as theoretical and practicum training for working with animals at Biosafety Level 2 (ABSL2). They also received PAPR training. The students worked with UTMB trainers Jason Hardcastle, Vickie Jones, Sheri Leavitt, and Belinda Rivera.

Gulf Coast Consortium Postdoctoral Veterinary Training Program - A clinical veterinarian from the Center for Comparative Medicine at Baylor College of Medicine in Houston and a veterinarian from the University of Texas Health Science Center in Houston who are participating in the Gulf Coast Consortium Postdoctoral Veterinary Training Program focused on Laboratory Animal Medicine and Science, attended PAPR training led by Jason Hardcastle and ABSL3 training led by Belinda Rivera and Nate Schueller. This training, which took place in January 2015, was well received and is anticipated to produce more students from the same program.



BSL and ABSL Safety Training -- A senior technologist and an assistant manager from Aga Khan University in Karachi, Pakistan, attended training at UTMB during January 2015. The students are shown here with trainer Sheri Leavitt.



NBTC ABSL trainers Nate Schueller, left, and Belinda Rivera, right, provided training to veterinarians focused on Laboratory Animal Medicine and Science in support of the Gulf Coast Consortium Postdoctoral Veterinary Training Program.

Baylor College of Medicine – In early 2015, collaboration continued with the Baylor College of Medicine in Houston, with students from that university attending training at the NBTC. In February, two postdoctoral researchers from Baylor's Department of Pediatrics attended BSL2 training led by NBTC's Jason Hardcastle. Later in the same month, an Assistant Professor and a Research Assistant from the National School of Tropical Medicine at Baylor and two clinical veterinarians from the Center for Comparative Medicine at Baylor attended PAPR training led by Jason Hardcastle and ABSL3 training led by Nate Schueller and Belinda Rivera.

Weill Cornell Medical College, Qatar – From March 3 – March 5, 2015, a Director from the Weill Cornell Medical College in Qatar attended BSL2 training at UTMB. This alliance is anticipated to grow, as the university is focused on delivering a world-class medical education, strongly enhanced by hands-on research experience in their laboratories. They are focused on accessing the best biosafety training available and have turned to the NBTC to assist their faculty and students with that endeavor.



Standards-based biological safety training involves hands-on practice, as shown by this student who traveled to Galveston from Qatar and the Weill Cornell Medical College.

University of Texas El Paso – In March 2015, UTMB welcomed the Director of Veterinary Services and a Research Assistant from the University of Texas at El Paso (UTEP) for BSL3 training led by Jason Hardcastle. UTEP, which is located on the border between Texas and Mexico, is a center of excellence for research on many of the emerging diseases that are impacting the animal and human populations in Mexico. The UTEP staff members returned to Galveston later in the month to complete PAPR training with Mr. Hardcastle and ABSL3 training with Belinda Rivera and Nate Schueller. They were joined by a veterinarian from Baylor College of Medicine who was participating in the Gulf Coast Consortium Postdoctoral Training Program in Laboratory Animal Medicine and Science.



UTMB Trainers Nate Schueller (left) and Belinda Rivera (right) with trainees from University of Texas El Paso and Baylor College of Medicine.

University of Wisconsin – Madison - An Associate Professor and PI from the Pediatrics Department at the University of Wisconsin – Madison in Madison, Wisconsin, attended three days of BSL3 training to prepare her for work at BSL3. Her training was led by NBTC trainer Vickie Jones. The training was customized for the researcher and designed to prepare her to safely perform research that will contribute to the knowledge of pediatric illnesses and that will benefit pediatric patients around the world. It focused on appropriate use of personal protective equipment and biosafety cabinets, as well as safe practices and procedures when working with BSL3 agents. The goal of the training was to provide her with the knowledge to share safe practices with her staff.



NIAID National Biocontainment/Regional Biocontainment Network Partners – Periodic training has been ongoing for a biosafety professional and the attending veterinarian from the Boston University National Emerging Infectious Disease Laboratories. The focus of this training has been on ensuring readiness for BSL4 safety, with training being provided by Corrie Ntiforo and Jet Newton, with support from the Galveston National Laboratory's attending veterinarian Dr. Curtis Klages. Both trainees completed ABSL4 training with Belinda Rivera and are in the process of completing 100 hour mentorships in the BSL4 facilities with the UTMB EHS and ARC staffs.

In April 2015, following the annual NBL/RBL Network meeting in Galveston, the Biosafety Officer from the Regional Biocontainment Laboratory at Colorado State University in Fort Collins, Colorado, attended ABSL3 training led by Belinda Rivera. The focus for her training was to familiarize her with the functions that laboratory personnel are performing in the labs with animals to help with her understanding of safety concerns and biocontainment procedures that are of critical importance. The training was designed to assist her in working with the ARC staff at Colorado State to ensure appropriate training and safety for all lab personnel.

From July 27 – July 31, 2015, the Senior Research Associate and a Research Analyst from Duke University's Regional Biocontainment Laboratory participated in ABSL3 training with Ms. Rivera. Their training was focused on preparing them to work with ferrets in BSL2 and BSL3 labs for influenza strain research that is about to commence at Duke. The trainees received comprehensive training that covered daily husbandry procedures and safe handling of ferrets, as well as technical training and hands-on practice with ferrets that ranged from tissue sampling and bleeding to necropsies.



Dr. Charles McGee, (left) Senior Research Associate from Duke University's RBL, and Christopher Sample, Research Analyst at Duke are shown with Belinda Rivera following their five day intensive ABSL training at the NBTC.



United Arab Emirates (UAE) Second Biosafety Conference – From April 27 to April 29, 2015, Dr. Anne-Sophie Brocard was in Abu Dhabi as an instructor for that nation’s major biosafety conference, which was attended by biosafety professionals from throughout the UAE. Dr. Brocard led a preconference session on laboratory safety and Personal Protective Equipment, as well as a one-day workshop for 40 researchers and laboratory directors. The conference was sponsored by the Ministry of Environment & Water in the UAE, as well as the Global Virus Network. *(Photo above.)*

Miscellaneous Training of Domestic Academic and Industry Professionals - Demand for training of domestic biocontainment laboratory professionals remains high, both at academic institutions throughout the United States and at industry laboratories. During the final quarter of this reporting period, several additional domestic training efforts were completed. They include:

May 5-May 7: Two PhD students from the University of Houston, Houston, Texas, attended BSL2 training led by Jason Hardcastle, with a focus on basic biosafety principles and the use of biosafety cabinets and PPE.

May 11- May 15: Vickie Jones traveled to Buffalo, New York, to provide BSL3 training to industry laboratory personnel, including one intern and three scientists from Calspan-University of Buffalo Research Center (CUBRC). The training was customized to ensure safe utilization of the equipment in their laboratories. This lab specializes in Chemical, Biological & Medical Sciences.

May 11- May 15: Belinda Rivera traveled to Indiana University in Bloomington, Indiana, where four laboratory animal resource personnel completed the ABSL3 course (theory and practicum) and twenty-four trainees from various departments completed the ABSL3 Theory Course.

June 30-July 2: An Analytical Development Scientist from Biotest Pharmaceuticals Corporation (BPC), Boca Raton, Florida, attended BSL2 training at the NBTC, led by Jason Hardcastle.

Aim 2: To provide the information and education necessary for a critical global discussion on the biosecurity, biosurety and related policy issues involved in the operation and maintenance of biocontainment facilities.

Students, staff, and faculty, as well as those working in the biocontainment field around the world share an interest in growing the knowledge base and the understanding of existing and developing policies in biosecurity, biosurety and policy issues as they relate to the operation and maintenance of biocontainment facilities. Representatives of UTMB and the Galveston National Laboratory continue to participate in national and international committees, providing leadership and information that contributes to the growing knowledge in the field.

External Advisory Committee, CDC - Dee Zimmerman, Biosafety Officer and Director of the Environmental Health and Biosafety Regulations and Requirements Core at the University of Texas Medical Branch, was selected to participate in a special external advisory committee charged with reviewing issues that occurred at the CDC laboratories in June 2014, with the goal of creating corrective protocols, safeguards, and training initiatives that can be implemented at biocontainment laboratories around the world. The group met periodically throughout 2014 and 2015, and recommendations from the group will be implemented in laboratories around the world.

World Health Organization, Emergency Committee on Ebola – Dr. James Le Duc participated as a member of the WHO's international committee that not only monitored the growing threat of Ebola in West Africa but that provided recommendations to government leaders in West Africa in hopes of slowing the spread of the current epidemic. Recommendations from this committee covered policy as well as safety and security suggestions and procedures. Dr. Le Duc also shared his insights and recommendations with U.S. government officials, elected officials on the state and federal level, and the general public through media interviews, guest editorials and presentations. International coverage of these activities was widespread.

West African Ebola Outbreak Outreach – Dr. Thomas Ksiazek spent six weeks in Sierra Leone in August and September 2014 leading a contact tracing team for the U.S. Centers for Disease Control and Prevention. Prior to, during his deployment, and since his return from Sierra Leone, his advice and counsel have been sought by national and international media and professional groups to help domestic and international health care professionals and policy makers increase their understanding of both the clinical and biocontainment requirements for dealing with Ebola. In addition, Dr. Ksiazek presented a lecture about the situation in Sierra Leone and the CDC's efforts to curtail the epidemic that was broadcast live on the internet as well as videotaped and placed on YouTube. Information about the video was shared with colleagues at biocontainment labs, regulatory agencies and response organizations. This outreach has continued throughout the year.

Topics in Biosecurity Seminar Series – In September 2014, Dr. Kavita Berger, Associate Director of the Center for Science, Technology and Security Policy for the American Association for the Advancement of Science in Washington, D.C., presented a lecture as part of this ongoing biosecurity seminar series, adding to the knowledge of scientists from around the world about how national and international science policy is created. She specifically focused on select agent rules, scientific funding, insider threats, and future policies under development, encouraging scientists to provide input that helps make science policies more effective and realistic.



Dr. James Le Duc presents a Certificate of Appreciation to Dr. Kavita Berger, of Washington, D.C. -based American Association for the Advancement of Science, who delivered a lecture entitled "Leveraging Science for Security: From Research to Diplomacy" to more than 100 students, faculty, and staff representing more than a dozen countries. Dr. Tara O'Toole, shown with Dr. Le Duc in the photo to the left, discussed major biosecurity issues that will face our nation and the world in coming years.



The December 2014 Topics in Biosecurity seminar featured Dr. Tara O'Toole, a professional who is a major part of the inner workings in Washington. Dr. O'Toole served as the Under Secretary for Science & Technology in the Department of Homeland Security under President Barack Obama from 2009 - 2013. She currently works with a major venture financing firm that links high technology companies to federal security agencies to provide new technologies that meet expanding security needs. Dr. O'Toole's presentation offered an interesting look at how biology and science will help to solve many of the biosecurity and healthcare-related problems that will face our nation in the coming years. In a private lunch with graduate students, she also provided insight into alternative careers for scientists.

Texas Task Force on Infectious Disease Preparedness and Response – Dr. Le Duc and Dr. Ksiazek were appointed by Texas Governor Rick Perry to a special task force charged with creating policies and recommendations for enhancing Texas' capabilities for preparing for and responding to pandemic disease, such as Ebola. The committee is charged with creating a strategic emergency response plan to deal with the biosecurity, public health, and medical issues involved in preparing for, responding to, and recovering from a public health threat. While the work of this group is state-specific, the policies and actions they recommended will have a wide-spread, national and international impact on policy development in the areas of infectious disease and public health protection and response.



Texas Governor Rick Perry, far right, converses with BSL4 Lab Manager Terry Juelich (in biocontainment suit), Dr. Brett Giroir of Texas A&M University, and Dr. Curtis Klages of UTMB about the in-depth training required to work with dangerous pathogens. Governor Perry visited the Galveston National Laboratory in October 2014 to tour the facility and to discuss the Texas Task Force on Infectious Disease Preparedness and Response, which provides policy direction for Texas, and by example, for public health agencies and policy makers around the world.

International Federation of Biosafety Associations -- Mr. Miguel Grimaldo, facilities engineer for the Galveston National Laboratory, traveled to Barcelona, Spain in late October 2014 at the invitation of the International Federation of Biosafety Associations. There he visited the Ciesa Laboratory at the Universitat Autònoma de Barcelona (UAB) to review operational procedures and provide suggestions for improvements. While in Spain, he also made a presentation to the growing association membership on the development of autoclave cycles for decontamination of laboratory waste and animal carcasses. The continued interest by members of the International Federation of Biosafety Associations is anticipated to lead to future training on site in Galveston for representatives from several member laboratories.

University of Melbourne – Collaboration and consultations continue with the University of Melbourne as the BSL4 laboratory being constructed there nears completion. Engineers and facility maintenance personnel from the University of Texas Medical Branch continue to consult with and advise their counterparts in Australia on best practices for the operation and maintenance of the high containment laboratory facilities where specimens from hemorrhagic fever within Australia will be brought for analysis and study. Additional collaborations and support are anticipated throughout 2015.

GOARN

Global Outbreak Alert and Response Network

Global Outbreak Alert and Response Network (GOARN) – UTMB continues to be an active participant in GOARN, currently focused on the Ebola crisis in West Africa. Representatives of the Galveston National Laboratory and the NBTC have provided leadership and counsel focused on ensuring the safety of laboratory workers, healthcare workers, military personnel, and volunteers who are working with patients and in research laboratories where laboratory samples are handled and analyzed.

USDA Training Course – Baltimore, MD – Mr. Miguel Grimaldo was an instructor at the 3rd USDA Agricultural Research Service International Biosafety and Biocontainment Symposium held in Baltimore, Maryland, in February 2015. He was one of five instructors who taught curricula during two pre-conference courses: Facility Operational Biosafety and Research and Diagnostic Facility Biosecurity: Operational Challenges and Solutions. Exposure at events such as this often lead to future collaborations and queries regarding customized training or participation in NBTC training programs. In this case, as a result of his teaching during this symposium, UTMB received an inquiry from the FDA Center for Biologics Evaluation & Research asking for personalized assistance in establishing protocols for shut-downs of animal facilities for HVAC inspections. Mr. Grimaldo is working with Dr. Marisa Hickey of the FDA in response to this request.

Victorian Infectious Disease Reference Laboratory – Melbourne, Australia – The Victorian Infectious Disease Reference Laboratory is another example of an institute with an ongoing collaboration with the University of Texas Medical Branch and the National Biocontainment Training Center. From March 30 – April 2, 2015, NBTC trainers and EHS consultants Corrie Ntiforo and Jet Newton traveled to Australia to provide a biosafety peer review and consultation on this newly constructed BSL4 facility. While there, they provided staff members with site specific BSL4 training.



Jet Newton (second from left) and Corrie Ntiforo (second from right) have developed an ongoing relationship with staff in Melbourne, Australia, who appreciate their expertise in BSL4 laboratory biosafety and operations.

National and International Policy Discussions – In recent months, with several high profile issues involving select agents making the news, professional organizations and committees have convened to develop strategies and plans for ensuring the ongoing safety of personnel, training of laboratory professionals, documentation of procedures and myriad other issues. Dr. Le Duc has been an active participant in many forums, ranging from NIAID's National Biocontainment/Regional Biocontainment Network to the National Academy of Sciences and the National Science Advisory Board for Biosecurity. These meetings will continue in both domestic and international forums, including a meeting in India in August 2015.

Aim 3. To Develop and implement a dedicated program to facilitate the establishment, maintenance and administrative oversight of operations of biocontainment facilities.

Biocontainment facilities are unique in their mechanical, security and safety infrastructures, and there are very few educational programs available that prepare professionals for their operational requirements. Today, with more international laboratories being constructed, the Galveston National Laboratory has taken on the role of sharing expertise on the unique engineering, maintenance and administrative challenges of running a safe biocontainment operation. The goal: to help ensure that all labs that deal with infectious pathogens operate safely.

While every facility is unique in the research being conducted and the pathogens being handled, there are general principles that must be followed. As a national resource with a large variety of research projects underway, the GNL, through the National Biocontainment Training Center, is in a unique position to share its expertise and lessons learned. Whether providing tours, one-on-one consultations, or formal training programs, the staff at the GNL is constantly sharing relevant, hands-on experience with the next generation of biocontainment industry leaders. An expanding list of the essential tools, skills and procedures critical to the safe and secure operations of a biocontainment laboratory are being compiled, documented, and shared to ensure that the best practices for fiscal stability, security, utility management, and equipment needs are available to biocontainment laboratories around the world.

Standards Development – Miguel Grimaldo participated on the American Biological Safety Association's Committee for the development of the 2014 ANSI Z9.14 Standard for the Performance verification of ventilation systems for BSL3 and ABSL3 Laboratories.

NBTC Fellowship - Dr. Han Xia – Dr. Xia is a graduate of the Chinese Academy of Sciences and came to UTMB from the Wuhan Institute of Virology. Dr. Xia's focus is on Crimean-Congo hemorrhagic fever, working under the mentorship of Dr. Dennis Bente. As she nears the end of her Fellowship, Dr. Xia continues to work with Dr. Bente in the BSL4 laboratory on the viral replication and pathogenicity *in vitro* and *in vivo* of CCHFV. She continues to receive ongoing training in high level biocontainment, as well as individualized training on the management of a high containment laboratory and oversight responsibilities and training requirements for personnel. She plans to use her operational knowledge upon her return to China. In October 2014, Dr. Bente and Dr. Xia traveled to the Wuhan Institute of Virology in China to share information on the work taking place in Galveston on Ebola and other filoviruses and to provide an update on Dr. Xia's work on Crimean-Congo hemorrhagic fever.

Dr. Han Xia, a second year NBTC Fellow (shown in both pictures to the right) works with her mentor Dr. Dennis Bente on documentation for equipment and other operational issues encountered during research being done in the BSL-4 lab at UTMB. Dr. Xia has been involved in groundbreaking work on Crimean-Congo Hemorrhagic Fever.



Mr. Miguel Grimaldo, an expert on biocontainment engineering, is shown here at the podium during his presentation to the Mexican Biological Safety Association in June 2015.

Mexican Biological Safety Association (AMEXBIO), Mexico City – In June 2015, Mr. Grimaldo participated at the 7th International Symposium of Biosafety and Biosecurity where he taught an 8-hour class at the Pre-Symposium activities on “Critical Elements in the Operation on a BSL3 Laboratory.” During the Symposium, Mr. Grimaldo provided a talk about the new ANSI Z9.14 Standard for Testing and Performance Verification Methodologies for Ventilation Systems for BSL3 and ABSL3 Laboratories.

Gorgas Memorial Research Institute, Panama – Mr. Grimaldo traveled in May 2015, and then again in July 2015, to participate in meetings with members of the Institute to discuss and advise about future infrastructure needs. The Gorgas Institute has a longstanding scientific collaboration with UTMB, and deteriorating infrastructure at the Institute in Panama has hampered administrative and research operations for the facility. Representatives from Gorgas will be working to implement recommendations provided by Mr. Grimaldo to ensure ongoing safety and security at the facility.

The Instituto Nacional de Enfermedades Virales Humanas, Argentina – The NBTC has an ongoing relationship with this Institute, which first sent personnel for facilities engineering and operational training to Galveston in late 2013. In 2014 and 2015, they continue to rely upon the expertise of the GNL’s engineering staff for instruction and advice. Miguel Grimaldo consulted with research and engineering personnel from the Institute to assist with autoclave cycle validation studies based on standards developed and proven at the GNL. This support assists the Institute with its work on diagnostics, treatments, investigations and preventative measures for combatting infectious diseases, particularly chikungunya, dengue and hemorrhagic fevers. In July 2015, the collaboration continued with discussions on validation of autoclave decontamination cycles.

International training efforts result in ongoing collaborations with colleagues from around the world. Miguel Grimaldo (far right) consults regularly with his Argentinian colleagues. This photo was taken at the Instituto Nacional de Enfermedades Virales Humanas. Professionals there continue to seek direction from GNL staff.



Universidad Autonoma De Nuevo Leon, Monterrey, Mexico – Mr. Grimaldo visited the Department of Virology and Immunology in Monterrey, Mexico, as a follow-up to the training classes that were previously conducted for Nuevo Leon personnel at UTMB. His goal for the visit was to review the completed remodeling of a BSL3 laboratory, as well as to review and consult on the BSL3 and BSL4 cabinet labs that are currently under construction. While there, Mr. Grimaldo made additional recommendations for the laboratory build-outs. It is anticipated that future collaborations will include the sharing of SOPs and additional safety training for new personnel, which will be covered under Aim 1 of this award.

Institute of Medical Biology, Chinese Academy of Medical Sciences, Kunming, China – Dr. Curtis Klages, a veterinarian at the Galveston National Laboratory, and Mr. Miguel Grimaldo were invited to review the animal facilities at the Chinese Academy of Medical Biology and present information on BSL4 technical specifications and performance requirements. In addition, they were asked to provide training on Laboratory Management, Facility Operations and Facility Personnel Training. The pair traveled to China Sept. 2- 8, 2014. Collaborations continued throughout the year, with a focus on the specialized maintenance needs of high containment laboratories. Staff members from Kunming also traveled to Galveston in January 2015 for specialized engineering training.



Personnel from the Chinese Academy of Medical Sciences are shown here with Mr. Miguel Grimaldo and Dr. Curtis Klages in Kunming, China in September 2014. The consultations being provided to the Chinese are helping to ensure that solid engineering and stable operational practices are in place for this BSL4 laboratory.

National Institutes of Health Committees – Miguel Grimaldo is participating in a committee focused on updating the NIH’s Design Requirements Manual (DRM), which addresses best practices and design standards for high containment laboratory facilities. Both national and international institutions involved in the design and construction of high containment laboratories will utilize this manual as a valuable resource.

Standards Development and Implementation Guidelines – NBTC representatives continue to be called upon by both national and international colleagues for assistance in interpreting the implementation requirements for new standards for maintenance and operation of high containment laboratories. In particular, the 2014 ANSI Z9.14 Standard for Performance verification for ventilation systems for BSL3 and BSL4 laboratories continues to raise questions for maintenance and operations personnel.

National Biocontainment Laboratory/Regional Biocontainment Laboratory Network Meeting - Miguel Grimaldo participated in the steering committee and planning efforts for the two-day NBL/RBL Network Meeting, which was held in Galveston in April. His goal is to continue to provide leadership to regional biocontainment laboratories located at universities around the United States and the world, sharing best practices in operations and maintenance.



Representatives from 13 National and Regional Biocontainment Laboratories, NIAID, the NIH, the FBI, and the CDC converged in Galveston in April 2015 for an annual meeting focused on the safe operation of biocontainment laboratories.

Consulting - Mr. Grimaldo received a request to provide information on the waste decontamination for a children's Ebola isolation unit from Children's Hospital in Houston. He shared his expertise on autoclave operation with staff there.

China Center for Disease Control – Representatives from the Chinese equivalent of the US Centers for Disease Control & Prevention traveled to Galveston to meet with several representatives of the Galveston National Laboratory. Mr. Grimaldo spent several days working with the representatives to provide insight into the safe operation of high containment laboratories.

Aim 4. To develop and implement training opportunities that focus on the safe and secure operations of novel laboratory instrumentation being introduced into the biocontainment laboratory environment.

New instrumentation continues to make its way into biocontainment laboratories where highly dangerous pathogens are studied. At UTMB, as new instrumentation is utilized in high containment labs, special circumstances are documented with the goal of sharing it with students from the U.S. and international locales. Our team is continually documenting the use of new instruments and special precautions or concerns that come with using them in a high containment laboratory. For example, decontamination of novel instrumentation for service and maintenance remains a major challenge, as many vendors will not work on equipment once it has been in a BSL4 laboratory. Over the last year, the progress documented on the following pages was made on this Aim:

Doherty Institute, University of Melbourne, Australia – Engineering professionals from Sinclair Knight Merz (SKM)/Jacobs Engineering in Melbourne, Australia, spent time at the Galveston National Laboratory in July 2014 learning about the specialized air filter systems that ensure air quality and safety. Since that time, Mr. Grimaldo has provided Colin Sakinofsky and Jim Hargreaves of SKM, who are designing systems for the new biocontainment laboratories in Melbourne, with additional documentation and site information. In turn, Mr. Sakinofsky and Mr. Hargreaves have presented the information to other SKM employees, as well as to personnel from the laboratory and administrative staffs at the University of Melbourne. In October 2014, Mr. Leo K. Fincher-Johnson, a Construction Manager for Major Projects and Project Delivery with the University of Melbourne, and Mr. Neil Walz, an independent consultant working on the Standard Operating Procedures for the University of Melbourne's BSL4 laboratories, met with Mr. Grimaldo and his team in Galveston to receive assistance and instruction in conducting laboratory audits.



Both BSL3 and BSL4 laboratories are housed in this new multi-story facility located on the University of Melbourne campus. The newest BSL4 lab in the building will be used to diagnose hemorrhagic fever.

Biocontainment Training of IT Support Personnel – During this year, professionals from the NBTC and UTMB developed a training program for Information Technology personnel who work on equipment found in high containment laboratories. Training IT professionals to work on equipment inside the labs will save time and money and should eliminate the necessity of disposing of computer equipment when it is in need of repair. Information on this specialized training has been added to the operational training guides and is being shared with international personnel in charge of the operation and ongoing maintenance of high containment facilities.

Real-Time PCR Training – The UTMB Assay Development Services Division, in conjunction with the NBTC and the Galveston National Laboratory, sponsored a Real-Time PCR training session hosted by vendor Life Technologies on Oct. 1, 2014. The purpose of the session was to provide an introduction to Real-Time PCR to students, postdocs and staff working in the high containment laboratories. 15 participants, including international trainees, participated in this session, which reviewed applications for working with DNA, RNA and protein analysis. Trainees were introduced to procedures for mutation detection, single nucleotide polymorphisms, and high resolution melt, as well as the analysis of RNAs and gene expression.

Course Updates -- On an ongoing basis, as new instrumentation is adopted for use in biocontainment laboratories, information is documented so that it can be shared with students and trainees from both U.S. and international laboratories. Courses are constantly updated with information about new instrumentation and novel laboratory equipment. Reviews of all course outlines were made during this reporting period.

American Biological Safety Association – Dee Zimmerman taught a course at the ABSA conference in Charleston, South Carolina, on principles and practice of biological safety. The event was held Feb. 23 – 27, 2015, and was attended by 40 students from both the U.S. and other countries around the world.

Real-Time Plethysmography Training – While working on research projects within the BSL2 laboratories at the Galveston National Laboratory, scientists are documenting concepts and real world situations that are shared with students who will have the opportunity to work with this novel laboratory instrumentation. Dr. Johnny Peterson and Dr. William Lawrence support the efforts of the NBTC staff by providing their expertise on working with this novel instrumentation. They are sharing this information with trainees as opportunities arise.

Aim 5. To develop and implement policies, procedures and training programs for the safe and secure conduct of preclinical studies to be undertaken within biocontainment at biosafety laboratory levels 2, 3 and 4 (BSL-2, 3, 4) in compliance with the U.S. Food and Drug Administration (FDA) Good Laboratory Practice (GLP) regulations (21 CFR Part 58).

As mentioned in prior reports, a growing number of projects in the biocontainment laboratories at the GNL are for the purpose of developing diagnostic tests, drugs and vaccines for use in the recognition, treatment and prevention of biological terrorism threats and emerging infectious diseases. Major attention continues to be focused on Ebola due to the West African epidemic and concerns throughout the world.

The University of Texas Medical Branch Office of Regulated Nonclinical Studies continues to validate SOPs, procedures, and equipment to comply with 21 CFR Part 58, commonly referred to as Good Laboratory Practices. As these processes are conducted, information is being captured for inclusion in training programs that will be used with students to help ensure their understanding of the requirements for compliance with the FDA's Good Laboratory Practice (GLP) regulations.

Clinical & Translational Research Forum – On March 11, 2015, staff from the NBTC attended the 3rd Annual Clinical & Translational Research Forum hosted by the Institute for Translational Sciences at UTMB. The forum offered an opportunity for researchers to display the broad spectrum of research being performed at UTMB and to promote the resources available to facilitate their work. Staff from the NBTC set up a booth and provided information to researchers about the training they provide to support biosafety preparedness and to ensure the safe and secure conduct of studies taking place at biosafety laboratory levels 2, 3 and 4 in compliance with FDA GLP regulations.

UTMB/FDA Training – On April 28, 2015, 52 federal regulatory staff members attended the 3rd Annual UTMB/FDA Practical Exercise in a Mock BSL4 Training lab. The objectives of the course were to demonstrate practical differences between BSL2 and BSL4 laboratory environments. Participants took part in exercises involving laboratory procedures and focused on the intricacies of donning/doffing personal protective equipment specific to BSL2 and BSL4. The BSL2 portion was led by Vickie Jones and the BSL4 portion of the practical exercise was led by Corrie Ntiforo and Jet Newton.

CONCLUSIONS

Providing individualized training to both domestic and international biocontainment professionals who work in laboratories or who are responsible for operations and maintenance remains a key to ensuring national security. Our goal is to ensure that scientific pursuits and the development of diagnostics, vaccines and therapies to prevent or cure infectious diseases are conducted in a safe and secure fashion. We continue to work to build this international culture

of trust, collaboration, and transparency that enhances biosecurity around the world. The following chart provides comprehensive tracking of training provided through UTMB's National Biocontainment Center:

Total Training Units Provided from May 2009 through July 2015



Training Course/Module	May-Dec 2009	Jan-Dec 2010	Jan-Dec 2011	Jan-Dec 2012	Jan-Dec 2013	Jan-Dec 2014	Jan-July 2015	Total
BSL2 theoretical	107	144	251	160	133	165	90	1050
BSL2 hands-on	64	76	92	117	102	134	59	644
ABSL2 theoretical	N/A	1	79	149	284	116	60	689
ABSL2 hands-on	N/A	1	40	76	105	116	58	396
BSL3 theoretical	45	119	100	135	86	125	24	634
BSL3 hands-on	45	101	94	76	57	49	24	446
BSL3 mentorship	36	41	24	18	14	26	-	159
Class III cabinet theoretical (New course)	N/A	N/A	N/A	N/A	N/A	2	N/A	2
Class III cabinet hands-on (New course)	N/A	N/A	N/A	N/A	N/A	2	N/A	2
ABSL3 theoretical	29	55	47	73	76	36	44	360
ABSL3 hands-on	29	50	46	37	53	29	17	261
ABSL3 mentorship	N/A	N/A	38	19	26	34	2	119
BSL4 Training, orientation and mentorship	9	28	59	47	41	59	39	
ABSL4 program	N/A	N/A	N/A	N/A	N/A	18	15	33
Non-human primate theoretical	16	15	60	41	20	24	1	177
Non-human primate, hands-on	N/A	N/A	90	41	28	23	2	184
Non-human primate annual refresher	N/A	N/A	37	114	89	108	2	350
Animal handling certificates	N/A	N/A	22	75	39	27	6	169
Graduate Program	39	36	32	13	18	25	0	163
Introduction to Microbiology	18	0	6	4	0	0	0	28
Aerobiology	19	5	2	8	0	2	4	40
Autoclave	195	27	46	30	25	14	-	337
High Throughput Safety training	8	11	3	2	17	12	-	53
PAPR (respirator training)	N/A	10	49	52	78	82	21	292
ABSA/AFBSA courses*	84	175	87	207	181	137	40	911
Agent specific training	N/A	N/A	N/A	N/A	186	141	0	327
Specialized Biosafety course	N/A	N/A	N/A	N/A	N/A	71	N/A	71
Ebola response training	N/A	N/A	N/A	N/A	N/A	177	N/A	177
Total trained	743	895	1,304	1,494	1,658	1,754	508**	8,356

**Includes just seven months of 2015